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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/163,648	09/30/1998	SUSAN L. ACTON	MIA-025.02	5728

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INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS INC.
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EXAMINER

GUPTA, ANISH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/163,648	Applicant(s) ACTON ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked: Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 2-16 and 45-59.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: For the Written Description rejection, Applicants argue that the correct standard is that "if one skilled in the art would recognize the scope of what is claimed in view of the description." Applicants state that one can make the desired variants having at least 90% identity by the methods disclosed in the instant specification. Applicants state that they have provided a partial structure as well as bioactivity and thus the standard has been met.

Applicants arguments have been considered but not found persuasive.


Applicants have not provided a partial structure of the those peptides that have the claimed activity. As stated in the previous office action, the 90% homology of the SEQ ID NO: 2 is not static. Thus homologue can have variability from one to another. In essence, there is no core that each homologue must contain. Applicants have not identified any core, or "partial structure" that must be present for the desired activity. Much like *University of Rochester v. Searle & Co.*, Case No. 03-1304 (Fed. Cir., Feb. 13, 2004), Applicants have not provided any written description as to which 'peptides... have the desired characteristic.' Thus, unlike applicants contentions, the standard has not been met since one could not determine if Applicants were in possession of the entire scope of the claim.

For enablement, Applicants state that the disclosure provides the generation of each of the possible derivatives of SEQ ID NO:2. It is routine in the art to construct derivatives which are at least 90% homologous to a given sequence. Further, the disclosure sets forth the claimed bioactivity as well as assessing such activities. The combination of structure as well as activity distinguishes the present situation from that outlined as computer modeling.

Applicants arguments have been considered but have not been found persuasive.

As stated in the previous office action, the Webster's II dictionary defines undue as "exceeding the appropriate or normal: excessive." The specification does not provide any guidance as to how to go about choosing the peptides having 90% homology. The specification lacks complete guidance to direct one of ordinary skill in the art as which amino acids to delete, add, or substitute in the peptides sequence obtain the 90% homologous analog. A 90% variant of SEQ. ID. 2 has approximately 81 different amino acids relative to the native sequence. Thus a variant of at least 90% would include, at the very least, every species having between 1 and 81 amino acid changes from 20 naturally amino acids. The permutations are permitted are limitless. Thus, making each one of those variants and determining activity for each variant would be undue experimentation.

The rejection are maintained for the reasons set forth in the previous office action and the reasons set forth above.


ANISH GUPTA
PATENT EXAMINER